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Barbara Bryant

September 2, 2003

## Patent

Attorney's Docket No. P-089-US2

Customer No. 27038

## In re Patent Application of

LINSELL et al.

Group Art Unit: 1654

Application No.: 10/601,847

Examiner: Not yet assigned

Filed: June 23, 2003

For: GLYCOPEPTIDE CARBOXY-  
SACCHARIDE DERIVATIVES

Commissioner for Patents  
P. O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure as set forth in 37 CFR §1.56, Applicants hereby submit the following information in conformance with CFR §§1.97 and 1.98. Enclosed herewith is form PTO-1449 which lists documents for consideration by the Examiner. Copies of the cited documents are also enclosed herewith.

The filing of this Information Disclosure Statement shall not be construed as a representation that a search has been made (37 C.F.R. §1.97(g)), or as an admission that the information cited is, or is considered to be, material to patentability (37 C.F.R. §1.97(h)).

The documents listed as B2 and B3 on the enclosed form PTO-1449 were cited in the International Search Report mailed on December 27, 2001, for the corresponding PCT Application No. PCT/US01/13996. A copy of the International Search Report is enclosed herewith for the convenience of the Examiner.

Pursuant to 37 C.F.R. §1.98(a)(3)(i), a concise explanation of the relevance of the following non-English language document is provided:

- (1) WO 00/54751 (in German) discloses methods for preparing solid dosage forms of a polymer binding agent, an active agent and a cyclodextrin. This document contains an English-language abstract on the title page.

Consideration of the listed documents is respectfully requested. Additionally, the Examiner is respectfully requested to return an initialed copy of the enclosed form PTO-1449 to Applicants.

This Information Disclosure Statement is being filed before the mailing date of a first official action on the merits for this application and therefore, no fee or certification is required under 37 CFR §1.97(b). In the event that an Office Action is mailed prior to receipt of this paper, the Commissioner is hereby authorized to charge the requisite fees under 37 CFR §1.97(c) for submission of this paper to Deposit Account No. 50-0344.

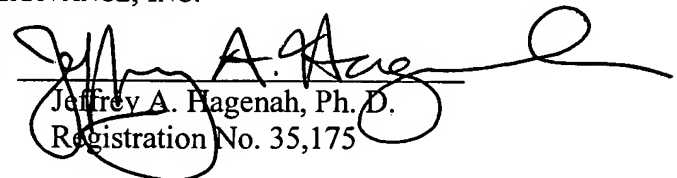
Should there be any questions concerning the cited documents, the Examiner is encouraged to telephone the undersigned agent for Applicants at (650) 808-6406 (direct).

Respectfully submitted,

THERAVANCE, INC.

Date: Sept. 2, 2003

By:

  
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Substitute for form 1449A/PTO		<b>Compleat if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)		Application Number	10/601,847
		Filing Date	June 23, 2003
		First Named Inventor	Martin S. LINSELL
		Art Unit	1654
		Examiner Name	Not yet assigned
Sheet 1 of 2	Attorney Docket Number	P-089-US2	

U.S. PATENT DOCUMENTS					
Examiner Initials *	Cite No. 1	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code <sup>2</sup> (if known)			
	A1	US-4,643,987	02-17-1987	Nagarajan et al.	
	A2	US- 4,698,327	10-06-1987	Nagarajan et al.	
	A3	US- 4,727,064	02-23-1988	Pitha	
	A4	US- 4,983,586	01-08-1991	Bodor	
	A5	US- 5,024,998	06-18-1991	Bodor	
	A6	US- 5,591,714	01-07-1997	Nagarajan et al.	
	A7	US- 5,602,112	02-11-1997	Rubinfeld	
	A8	US- 5,750,509	05-12-1998	Malabarba et al.	
	A9	US- 5,840,684	11-24-1998	Cooper et al.	
	A10	US- 5,916,873	06-29-1999	Cooper et al.	
	A11	US- 6,392,012 B1	05-21-2002	Judice et al.	
	A12	US- 6,444,786 B1	09-03-2002	Judice et al.	
	A13	US- 2002/0055464 A1	05-09-2002	Linsell et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials *	Cite No. 1	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)				
	B1	WO 94/12217	06-09-1994	Insite Vision Inc.		
	B2	WO 00/04044	01-27-2000	Princeton University		
	B3	WO 00/39156	07-06-2000	Advanced Medicine, Inc.		
	B4	WO 00/54751 (in German with English abstract)	09-21-2000	BASF Aktiengesellschaft		
	B5	WO 00/59528	10-12-2000	Trustees of Princeton Univ		
	B6	WO 01/83520 A2	11-08-2001	Advanced Medicine, Inc.		
	B7	WO 01/97851 A2	12-27-2001	Cubist Pharmaceuticals, Inc.		
	B8	WO 01/98326 A2	12-27-2001	Advanced Medicine, Inc.		
	B9	WO 01/98327 A2	12-27-2001	Advanced Medicine, Inc		
	B10	WO 01/98328 A2	12-27-2001	Advanced Medicine, Inc.		
	B11	WO 01/98329 A1	12-27-2001	Advanced Medicine, Inc.		
	B12	EP 0 667 353 A1	08-16-1995	Eli Lilly and Company		
	B13	EP 0 816 378 A1	01-07-1998	Eli Lilly and Company		

Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.



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Sheet	2	of	2	Attorney Docket Number	P-089-US2

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	C1	ALLEN et al., "The Role of Hydrophobic Side Chains as Determinants of Antibacterial Activity of Semisynthetic Glycopeptide Antibiotics", The Journal of Antibiotics, Vol. 50, No. 8, pp 677-684 (1997)	
	C2	GE et al., "Vancomycin Derivatives That Inhibit Peptidoglycan Biosynthesis Without Binding D-Ala-D-Ala", Science, Vol. 284, pp 507-511 (1999)	
	C3	NAGARAJAN et al., "Synthesis and Antibacterial Evaluation of N-Alkyl Vancomycins", The Journal of Antibiotics, Vol. XLII, No. 1, pp 63-72 (1989)	
	C4	NICOLAOU et al., "Chemistry, Biology, and Medicine of the Glycopeptide Antibiotics", Angew. Chem. Int. Ed., Vol. 38, pp 2097-2152 (1999)	
	C5	PAVLOV et al., "A New Type of Chemical Modification of Glycopeptides Antibiotics: Aminomethylated Derivatives of Eremomycin and Their Antibacterial Activity", The Journal of Antibiotics, Vol. 50, No. 6, pp 509-513 (1997)	
	C6	PAVLOV et al., "Chemical Modification of Glycopeptide Antibiotics", Russian Journal of Bioorganic Chemistry, Vol. 24, No. 9, pp 570-587 (1998)	
	C7	PAVLOV et al., "Mono and Double Modified Teicoplanin Aglycon Derivatives on the Amino Acid No. 7; Structure-activity Relationship", The Journal of Antibiotics, Vol. 51, No. 1, pp 73-78 (1998)	
	C8	ZHANG et al., "A review of recent applications of cyclodextrins for drug discovery", Expert Opinion on Therapeutics Patents, Vol. 9, No. 12, 21 pages (1999)	

Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.